

### General

#### Title

Inflammatory bowel disease (IBD): percentage of patients aged 18 years and older with a diagnosis of IBD for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-tumor necrosis factor (TNF) therapy.

#### Source(s)

American Gastroenterological Association (AGA). Inflammatory bowel disease (IBD): testing for latent tuberculosis (TB) before initiating anti-TNF (tumor necrosis factor) therapy. Bethesda (MD): American Gastroenterological Association (AGA); 2015 Dec 18. 8 p.

#### Measure Domain

#### Primary Measure Domain

Clinical Quality Measures: Process

# Secondary Measure Domain

Does not apply to this measure

# **Brief Abstract**

## Description

This measure is used to assess the percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) for whom a tuberculosis (TB) screening was performed and results interpreted within 6 months prior to receiving a first course of anti-tumor necrosis factor (TNF) therapy.

#### Rationale

Before initiating biologic anti-TNF (tumor necrosis factor) therapy for a patient with inflammatory bowel disease (IBD), it is essential to screen the patient for tuberculosis (TB), as research has documented a higher incidence of TB after anti-TNF therapy. All patients being considered for biologic anti-TNF therapy should receive a tuberculin skin test, even if the patient has previously received the Bacille Calmette-Guérin (BCG) vaccination. Test results, in addition to patient risk for TB and other tests, should be used to assess the patient's risk for latent TB infection. This is a patient safety measure.

Opportunity for improvement: While there are a limited number of studies that investigate gaps in care for patients with IBD, the research that does exist identifies opportunities for improvement in care areas:

1) there is a lack of adherence to tuberculosis screening, most noticeably in the use of disease-modifying anti-TNF drugs, and 2) variations in care by practice setting, geographic region and physician specialty.

Golimumab, certolizumab pegol, infliximab and adalimumab may all trigger latent TB. Also, all patients should be monitored during therapy for active TB even if the initial latent TB testing is negative.

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are taking TNF blocker medicines (Kaiser et al., 2009).

#### Clinical Recommendation Statements:

Prior to commencing treatment with anti-TNF, all patients should be screened for TB in accordance with the British Thoracic Society (BTS) guidelines. Active TB needs to be adequately treated before anti-TNF therapy can be started. Prior to commencing anti-TNF therapy, consideration of prophylactic anti-TB therapy (as directed by the BTS guidelines) should be given to patients with evidence of potential latent disease (past history of TB treatment or abnormal chest X-ray raising the possibility of TB) after consultation with a local TB specialist. All patients commenced on anti-TNF therapies need to be closely monitored for TB (Ledingham, Deighton, & British Society for Rheumatology Standards, Guidelines and Audit Working Group, 2005).

In an immunocompromised person (adult or child), the tuberculin skin test (TST) should be the initial test used to detect latent TB infection (LTBI). If the TST is positive, the person should be considered to have LTBI.

However, in light of the known problem with false-negative TST results in immunocompromised populations, a clinician still concerned about the possibility of LTBI in an immunocompromised person with a negative initial TST result may perform an interferon-gamma release assay (IGRA) test. If the IGRA result is positive, the person might be considered to have LTBI. If the IGRA result is indeterminate, the test should be repeated to rule out laboratory error. If the repeat test is also indeterminate, the clinician should suspect anergy and rely on the person's history, clinical features, and any other laboratory results to make a decision as to the likelihood of LTBI. Although both IGRAs may be used as described above, there is evidence that the T-SPOT.TB assay may be more sensitive than the QuantiFERON-TB Gold In-Tube (QFT-GIT) assay in active TB, and this characteristic might be especially relevant in immunocompromised populations. While the approach of accepting either test result (TST or IGRA) as positive will improve the sensitivity of detecting LTBI in immunocompromised populations, there are no data supporting the efficacy of preventive therapy in TST-negative but IGRA-positive individuals. Thus the clinician must weigh the potential benefit of detecting more persons with positive test results against the lack of evidence for the benefit of preventive therapy in such persons (Canada Tuberculosis Committee [CTC], 2008).

Infliximab can reactivate latent HBV (Esteve et al., 2004).

#### Evidence for Rationale

American Gastroenterological Association (AGA). Inflammatory bowel disease (IBD): testing for latent tuberculosis (TB) before initiating anti-TNF (tumor necrosis factor) therapy. Bethesda (MD): American Gastroenterological Association (AGA); 2015 Dec 18. 8 p.

Canadian Tuberculosis Committee (CTC). Updated recommendations on interferon gamma release assays for latent tuberculosis infection. An Advisory Committee Statement (ACS). Can Commun Dis Rep. 2008 Oct;34(ACS-6):1-13. PubMed

Kaiser T, Moessner J, Patel K, McHutchison JG, Tillmann HL. Life threatening liver disease during treatment with monoclonal antibodies. BMJ. 2009;338:b508. PubMed

Ledingham J, Deighton C, British Society for Rheumatology Standards, Guidelines and Audit Working Group. Update on the British Society for Rheumatology guidelines for prescribing TNFalpha blockers in adults with rheumatoid arthritis (update of previous guidelines of April 2001). Rheumatology (Oxford). 2005 Feb;44(2):157-63. PubMed

#### Primary Health Components

Inflammatory bowel disease (IBD); tuberculosis (TB) screening; latent TB; anti-TNF (tumor necrosis factor) therapy

#### **Denominator Description**

All patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) (see the related "Denominator Inclusions/Exclusions" field)

#### **Numerator Description**

Patients who had tuberculosis (TB) screening performed and results interpreted, within 6 months prior to receiving a first course of anti-tumor necrosis factor (TNF) therapy (see the related "Numerator Inclusions/Exclusions" field)

# Evidence Supporting the Measure

## Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

## Additional Information Supporting Need for the Measure

Unspecified

## **Extent of Measure Testing**

Unspecified

# State of Use of the Measure

#### State of Use

Current routine use

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not defined yet

# Application of the Measure in its Current Use

#### Measurement Setting

Ambulatory/Office-based Care

#### Professionals Involved in Delivery of Health Services

not defined yet

#### Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

#### Statement of Acceptable Minimum Sample Size

Specified

#### **Target Population Age**

Age greater than or equal to 18 years

## **Target Population Gender**

Either male or female

# National Strategy for Quality Improvement in Health Care

# National Quality Strategy Aim

Better Care

# National Quality Strategy Priority

Making Care Safer

Prevention and Treatment of Leading Causes of Mortality

# Institute of Medicine (IOM) National Health Care Quality Report Categories

#### IOM Care Need

Living with Illness

#### **IOM Domain**

Effectiveness

Safety

# Data Collection for the Measure

#### Case Finding Period

The reporting period (January 1 through December 31)

#### **Denominator Sampling Frame**

Patients associated with provider

#### Denominator (Index) Event or Characteristic

Clinical Condition

Encounter

Patient/Individual (Consumer) Characteristic

#### **Denominator Time Window**

not defined yet

## Denominator Inclusions/Exclusions

Inclusions

All patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD)

Denominator Criteria (Eligible Cases):

Patients aged greater than or equal to 18 years on date of encounter

AND

Diagnosis for IBD (International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] codes): K50.00, K50.011, K50.012, K50.013, K50.014, K50.018, K50.019, K50.10, K50.111, K50.112, K50.113, K50.114, K50.118, K50.119, K50.80, K50.811, K50.812, K50.813, K50.814, K50.818, K50.819, K50.90, K50.911, K50.912, K50.913, K50.914, K50.918, K50.919, K51.00, K51.011, K51.012, K51.013, K51.014, K51.018, K51.019, K51.20, K51.211, K51.212, K51.213, K51.214, K51.218, K51.219, K51.30, K51.311, K51.312, K51.313, K51.314, K51.318, K51.319, K51.40, K51.411, K51.412, K51.413, K51.414, K51.418, K51.419, K51.50, K51.511, K51.512, K51.513, K51.514, K51.518, K51.519, K51.80, K51.811, K51.812, K51.813, K51.814, K51.818, K51.819, K51.90, K51.911, K51.912, K51.913, K51.914, K51.918,

AND

Patient encounter during the reporting period (refer to the original measure documentation for specific Current Procedural Terminology [CPT] codes)

AND

Patients receiving a first course of anti-TNF (tumor necrosis factor) therapy: G8868

Exclusions

None

#### Exclusions/Exceptions

not defined yet

#### Numerator Inclusions/Exclusions

Inclusions

Patients who had tuberculosis (TB) screening performed and results interpreted, within 6 months prior to receiving a first course of anti-tumor necrosis factor (TNF) therapy\*

\*First Course of Anti-TNF Therapy: The first (ever) course of anti-TNF therapy

**Exclusions** 

Documentation of medical reason(s) for not performing TB screening test within 6 months prior to receiving a first course of anti-TNF therapy (e.g., patient positive for TB and documentation of past treatment; patient recently completed course of anti-TB therapy)

Documentation of patient reason(s) for not performing TB screening test within 6 months prior to receiving a first course of anti-TNF therapy (e.g., patient declined)

# Numerator Search Strategy

Fixed time period or point in time

#### Data Source

Administrative clinical data

Registry data

## Type of Health State

Does not apply to this measure

# Instruments Used and/or Associated with the Measure

Unspecified

# Computation of the Measure

#### Measure Specifies Disaggregation

Does not apply to this measure

### Scoring

Rate/Proportion

#### Interpretation of Score

Desired value is a higher score

#### Allowance for Patient or Population Factors

not defined yet

#### Standard of Comparison

not defined yet

# **Identifying Information**

#### **Original Title**

Measure #274: inflammatory bowel disease (IBD): testing for latent tuberculosis (TB) before initiating anti-TNF (tumor necrosis factor) therapy.

#### Measure Collection Name

Inflammatory Bowel Disease

#### Submitter

American Gastroenterological Association - Medical Specialty Society

# Developer

American Gastroenterological Association - Medical Specialty Society

Physician Consortium for Performance Improvement® - Clinical Specialty Collaboration

# Funding Source(s)

Unspecified

# Composition of the Group that Developed the Measure

Unspecified

#### Financial Disclosures/Other Potential Conflicts of Interest

Unspecified

#### Measure Initiative(s)

Physician Quality Reporting System

### Adaptation

This measure was not adapted from another source.

# Date of Most Current Version in NQMC

2015 Dec

#### Measure Maintenance

Unspecified

#### Date of Next Anticipated Revision

2017

#### Measure Status

This is the current release of the measure.

# Measure Availability

Source not available electronically.

For more information, contact the American Gastroenterological Association (AGA) at 4930 Del Ray Avenue, Bethesda, MD 20814; Phone: 301-654-2055; Fax: 301-654-5920; E-mail: measures@gastro.org; Web site: www.gastro.org

# NQMC Status

This NQMC measure summary was completed by ECRI Institute on March 14, 2016. The information was verified by the measure developer on March 29, 2016.

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## **Production**

# Source(s)

American Gastroenterological Association (AGA). Inflammatory bowel disease (IBD): testing for latent tuberculosis (TB) before initiating anti-TNF (tumor necrosis factor) therapy. Bethesda (MD): American Gastroenterological Association (AGA); 2015 Dec 18. 8 p.

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